K021422
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9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
Quality Program Manager
Cardiac and Monitoring Systems
Philips Medical Systems
3000 Minuteman Road
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This summary was prepared on May 1, 2002.

The name of this device is the PIC Software Release D.02.

- PIC Software, Release D.02
- Application Server Software, Release A.0
- UDP Server Software, Release A.0
- TCP/IP PC Client Software, Release A.0
- UDP PC Client Software, Release A.0.

2. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Panel 74 Cardiovascular	None	74 MHX	Physiological Monitor, Patient Monitor
	870.1025, III	74 DSI	Arrhythmia Detector and Alarm
	870.1025, III	74 MLD	Monitor, ST Alarm
	870.2800, II	74 DSH	Recorder, Magnetic Tape, Medical
	870.2300, II	74 MSX	System, Network and Communication, Physiological Monitors

3. The new device is substantially equivalent to the previously cleared HP CentralVue Software device marketed pursuant to K964832, K993171, K993907, K001057, and K011093.

4. The modification is a software-based change that adds tabular trends to the trend review capability and permits ICA compatible applications to be served to both PIC Software and other clients.

5. The new device has the same intended use as the legally marketed predicate devices. They are used to display physiologic waves, parameters and, trends, to format data for compliant strip chart recorders, to format data for printed reports, and the secondary annunciation of alarms for up to 16 patients from other networked medical devices at a centralized location. To provide retrospective review of alarms, physiologic waves and parameters. And to provide

primary annunciation of alarms, and configuration and control access for networked telemetry monitors at a centralized location.

6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities established the performance, functionality, and reliability characteristics of the new device with respect to the predicates. Testing involved system level tests, integration tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the software functionality meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 5 2002

Ms. Dave Osborn
Quality Program Manager
Philips Medical Systems
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01810-1099

Re: K021422
Trade Name: Philips M3290A Information Center Software, Revision D.02
Philips M2387A Application Server Software for M2385A, Release A.0
Philips M2389A UDP Server Software, Release A.0
Philips M2390A TCP/IP PC Client, Release A.0
Philips M2391A UDP PC Client, Release A.0
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: May 2, 2002
Received: May 3, 2002

Dear Mr. Osborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021422

510(k) Number (if known): K021422

Device Name: Philips M3290A Information Center Software, Release D.02
Philips M2387A Application Server Software for M2385A, Release A.0
Philips M2389A UDP Server Software, Release A.0
Philips M2390A TCP/IP PC Client, Release A.0
Philips M2391A UDP PC Client, Release A.0

Indications for Use: For central monitoring of adult, pediatric, and neonatal patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021422